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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,686	02/14/2002	Yoshiharu Matahira	00225CIP/HG	2395

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EXAMINER
OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/076,686	Applicant(s) MATAHIRA ET AL.	
	Examiner Clinton Ostrup	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/558,487* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-15 are pending in this application.

Priority

This application is a Continuation in Part of US 09/558,487, filed April 25, 2000 and claims priority to Japanese Application Number 225245/99, filed August 9, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “natural-type” in claims 1-2 and 4-5 is a relative term, which renders the claim indefinite. The term "natural-type" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "natural-type" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "type"), thereby rendering the scope of the claims unascertainable.

The phrase "by weight " in Claims 1, 2, and 4-6 is a relative phrase which renders the claims indefinite. The term "by weight" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

invention. It is unclear what the percentages by weight are based upon. For examination purposes the examiner assumed the percent by weight was based on the total weight of the composition.

Any remaining claims are rejected as depending on indefinite base claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 and 22 of copending Application No. 09/558,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to a method of skin care comprising orally administering a skin care agent comprising N-acetylglucosamine obtained or obtainable by the hydrolysis of chitin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 7-9 rejected under 35 U.S.C. 102(b) as being anticipated by Burton et al., 5,217,962. Burton et al teach the use of N-acetylglucosamine as a cytoprotective agent for persons afflicted with psoriasis by treating said persons by oral administration a therapeutic amount of N-acetylglucosamine, or a pharmaceutically acceptable salt thereof on a periodic basis. The reference teaches that the novelty of their invention is the ingestion of N-acetylglucosamine to rectify the disorder of psoriasis without being topically applied. See: col. 2, line 51 – col. 3, line 10. Furthermore, In Example 2, J.F. dissolves the N-acetylglucosamine in fruit juice, thus meeting the specific requirements of instant claims 7-9. See: col.6, line 45 –col. 7, line 30 and abstract. Thus, Burton et al., clearly teach a composition comprising N-acetylglucosamine being orally administered in the form of a beverage as claimed instantly in claims 1-3 and 7-9.

Claims 1-3 and 9 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Murad 5,804,594.

Murad teaches N-acetylglucosamine in an orally administered pharmaceutical composition for the treatment of skin conditions. The reference teaches the composition in the form of capsules and tablets and containing amounts of N-acetylglucosamine that overlap those as claimed instantly in claims 1-3. See: col.1, line 25 – col. 3, line 56; col. 8, line 43 – col. 10, line 40, claims 13-19.

Although the primary references do not specifically teach their N-acetylglucosamine as being "natural-type" or **obtainable by hydrolysis of chitin with an acid, an enzyme, or an acid or an enzyme,** Haynes et al., 5,998,173 is being supplied as a teaching reference to show that N-acetylglucosamine can clearly be made by such as process. Furthermore, the instant claims do not require the N-acetylglucosamine be obtained by any such methods, only that it is **obtainable** by said methods.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton et al., 5,217,962 as applied to claims 1-3 and 7-9 above and further in view of Matsuura et al., JP 01268618A taken together with Haynes et al., 5,998,173.

Burton et al teach the use of N-acetylglucosamine as a cytoprotective agent for persons afflicted with psoriasis by treating said persons by oral administration a therapeutic amount of N-acetylglucosamine, or a pharmaceutically acceptable salt thereof on a periodic basis. The reference teaches that the novelty of their invention is the ingestion of N-acetylglucosamine to rectify the disorder of psoriasis without being topically applied. See: col. 2, line 51 – col. 3, line 10. Furthermore, In Example 2, J.F. dissolves the N-acetylglucosamine in fruit juice, thus meeting the specific requirements of instant claims 7-9. See: col.6, line 45 –col. 7, line 30 and abstract. Thus, Burton et

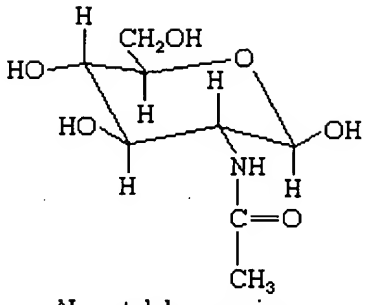
al., clearly teach a composition comprising N-acetylglucosamine being orally administered in the form of a beverage as claimed instantly in claims 1-3 and 7-9.

Although the primary reference teaches a method of skin care comprising orally administering N-acetylglucosamine and pharmaceutically acceptable carriers, including food products such as juices, the primary reference lacks the chitin oligosaccharide as claimed instantly in claims 4-6 and 10-15.

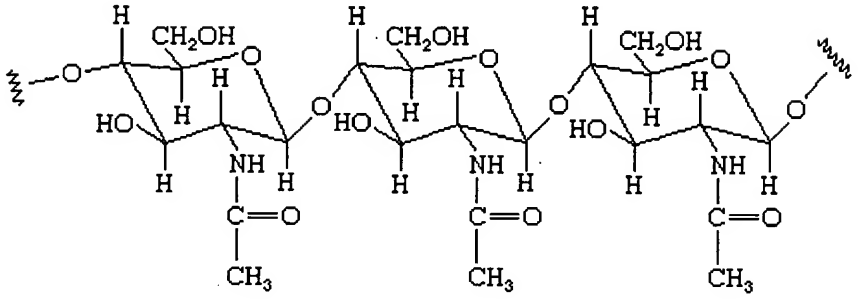
Matsuura et al., JP 01268618A teach a cosmetic composition containing a chitin oligosaccharide for imparting remarkable softening and humectant effects to the skin or hair. See: abstract.

Haynes et al., teach a method of producing N-acetyl-D-glucosamine by the enzymatic hydrolysis of chitin. Haynes teaches a method of producing N-acetyl-D-glucosamine in an economic, highly efficient process by hydrolyzing chitin. See: col. 1, lines 5-10 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the methods of skin treatment as taught by Burton et al by adding a chitin oligosaccharide as taught by Matsuura et al., particularly given that chitin is a polymer of *N*-**acetylglucosamine**, a sugar that contains an amide functional group, and the sugar units in chitin are linked by β -1,4□glucosidic bonds:



N-acetylglucosamine



chitin

and the method of producing N-acetylglucosamine as taught by Haynes et al., is rate-limited by the enzyme that produces N-acetylglucosamine from chitin and Haynes et al., teach that chitobiose and chitotriose are secondary and tertiary products when forming N-acetylglucosamine. Therefore one would have been motivated to add chitin oligosaccharides to the composition Burton et al. for the added benefits of said oligosaccharides touted by Matsuura et al and the fact that the cost efficient processes of obtaining N-acetylglucosamine of Haynes et al., teaches them as secondary and tertiary products in the formation of N-acetylglucosamine.

Furthermore obtaining N-acetylglucosamine by the hydrolysis of chitin as taught by Haynes et al., and Haynes teaches that N-acetylglucosamine is obtained by an economic, highly efficient method by hydrolyzing natural, abundant materials to produce said N-acetylglucosamine in an environmentally friendly manner. Furthermore, in regard to a "natural-type N-acetylglucosamine," N-acetylglucosamine is the same

chemical compound regardless of how it is derived and none of the instant claims require N-acetylglucosamine to be obtained from hydrolyzed chitin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

April 15, 2003